

# Ultrasound-guided vacuum-assisted core biopsy in the diagnosis and treatment of focal lesions of the breast – own experience

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## Abstract

**Introduction:** Vacuum-assisted core biopsy (VACB) guided by ultrasound is a minimally invasive method used in diagnosis and treatment of breast focal lesions. Vacuum-assisted core biopsy is an interesting minimally invasive alternative to open surgical biopsy.

**Aim:** To assess the value of ultrasound-guided vacuum-assisted core biopsy in the diagnosis and treatment of breast focal lesions.

**Material and methods:** In the period 2009-2010, 397 ultrasound-guided vacuum-assisted core biopsies were performed. Mean age of the patients was 41.7 years (18-92 years), and size of the lesions ranged from 3 mm to 65 mm, mean size being 12 mm. All women with diagnosed atypical ductal hyperplasia or cancer were qualified for surgery. The patients with histopathologically benign lesions were under follow-up.

**Results:** Samples sufficient for histopathological examination were obtained from 394 cases (99.2%). Of all 397 lesions, 293 (73.7%) were diagnosed as benign, there were 6 (1.6%) cases of atypical ductal hyperplasia and 98 (24.7%) malignant lesions. Three hundred and sixty-nine lesions were below 15 mm in diameter, of which 339 (91.9%) were totally removed during the VACB.

**Conclusions:** The results obtained confirm high efficiency of ultrasound-guided VACB in the differential diagnosis of breast focal lesions, including impalpable ones. It is a safe method with a low complication rate. In the case of benign lesions with a diameter not exceeding 15 mm, it allows one to excise the whole lesion and is a very good alternative to an open surgical biopsy. Vacuum-assisted core biopsy should be a standard and the method of choice in diagnosing breast lesions.

**Key words:** vacuum-assisted core biopsy, breast cancer, breast focal lesions.

## Introduction

Vacuum-assisted core biopsy (VACB), also known as mammotome biopsy, is a minimally invasive method used in diagnosis and treatment of breast focal lesions. Vacuum-assisted core biopsy was first performed on the 5<sup>th</sup> of August, 1995 in Denver, USA. Since 1996 it has been used in Europe and since 1999 in Poland [1]. Mammotome biopsy can be performed under the guidance of ultrasound or mammography

(stereotaxic biopsy), and recently also under MR guidance [2]. Various advantages of VACB have made it a commonly used procedure in diagnosing breast lesions [3, 4]. It is a safe, well tolerated by patients and minimally invasive method that does not require hospital stay. It causes minimal to no scarring and does not deform the breast. Vacuum-assisted core biopsy allows removal of multiple tissue samples in a single attempt in a relatively short time and the patient is able to quickly return to work.

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Vacuum-assisted core biopsy is primarily a diagnostic method. Focal lesions in the breast requiring histopathological examination are the primary indication for this procedure. In some cases, the method can be used therapeutically. It is not used to treat malignant lesions because the samples obtained in this way are fragmented, which makes it impossible to precisely establish the margin of removed tissue. However, with small benign lesions, the method is currently an interesting minimally invasive alternative to open surgical biopsy [5].

## Aim

The aim of this study is to assess the value of ultrasound-guided vacuum-assisted core biopsy in the diagnosis and treatment of breast focal lesions.

## Material and methods

We analyzed the results of 397 ultrasound-guided vacuum-assisted core biopsies performed in 2009-2010 in the Regional Out-patient Clinic of Early Diagnosis and Treatment of Breast Diseases at the Clinical Ward of General, Oncological and Gastroenterological Surgery of the University Hospital in Krakow.

All women enrolled in the study underwent ultrasonographic examination and women over 40 years of age also underwent mammography. All breast lesions were classified ultrasonographically as BIRADS category 3, 4a, 4b, 4c, 5. Ultrasonographic examination was performed with LOGIQ 5 equipment using a 10 MHz linear probe. Before each biopsy blood clotting parameters were checked. A 2-3 mm incision in the skin was made before inserting a 10G needle (Encor). The mean number of samples obtained from a single insertion was 9 (5-17). Biopsy was performed with the patient laying on her back under local anesthesia with 1% Lignocaine prior to the start of the procedure. The procedure lasted from 10 min to 20 min. Compression of approximately 5 min duration was used immediately following the removal of the biopsy device. No sutures were used. Pressure dressing was used routinely over the breast for 24 h following the procedure. All vacuum-assisted core biopsies and surgical excisions were performed by the same experienced surgeons. A pathologist examined the samples in the laboratory of the Chair of Pathomorphology of the Jagiellonian University Medical College.

Vacuum-assisted core biopsy was used to obtain histopathological diagnosis of the breast lesions.

Therapeutic excision of lesions up to 15 mm in diameter with low risk of malignancy (BIRADS category 3 and 4a) was done routinely during the biopsy. In case of suspected malignant lesions biopsy verified the diagnosis and defined the receptor status of the tumor, necessary for optimal planning of the treatment. Whenever there was a high suspicion of a malignant process (BIRADS category 4b, 4c, 5) and the diameter of the lesion was less than 10 mm, gel-titanium breast tissue marker was used as a routine measure.

The patients with histopathological diagnosis of benign lesions were followed up with clinical and ultrasound examination after 3 and 6 months, and then annually. All women with atypical ductal hyperplasia (ADH), ductal carcinoma in situ (DCIS) or invasive cancer were qualified for surgical excision.

The follow-up period ranged from 14 to 38 months, 25 months on average. Patients who refused to give informed consent to VACB, had allergy to local anesthetics, and those with active skin infections on the breast were disqualified.

## Results

The mean age of the patients was 41.7 years (18-92 years). The size of the biopsied lesions ranged from 4 mm to 65 mm (mean: 12 mm). The analyzed parameters including the location of the lesion in the breast, clinical features, as well as ultrasonographic and histopathological findings, are shown in Table I. Morphology of breast lesions qualified for ultrasound-guided VACB and their classification according to BIRADS are shown in Table II.

During the first biopsy, an adequate number of samples for the histopathological examination was obtained from 394/397 patients (99.2%). In 3 cases the result was nondiagnostic. These patients underwent repeat biopsy and histopathological examination revealed fibrocystic lesions. Among 397 focal lesions detected, there were 293 (73.7%) benign lesions, 6 cases of atypical hyperplasia (1.6%), and 98 malignant lesions (24.7%). Of all 98 cancers diagnosed by biopsy, 28 were impalpable (28.6%).

Of 369 lesions below 15 mm in diameter, 339 (91.9%) were entirely removed during VACB. Excision was incomplete in 30 patients with benign lesions (22 fibroadenomas, 6 fibrocystic lesions, 2 hyperplastic lesions without atypia) and no recurrence or malignant process was revealed in the follow-up.

**Table I.** Clinical and morphological features of the biopsied breast lesions

Clinical and morphological features of the biopsied breast lesions	No. of patients	Percentage of patients
Right breast	190	48
Left breast	207	52
Superior lateral quadrant	163	41
Superior medial quadrant	79	20
Inferior lateral quadrant	131	33
Inferior medial quadrant	24	6
Size of lesion (longest size in ultrasound) [mm]:		
< 15	369	92.9
> 15	28	7.1
Impalpable lesion	358	90.1
Palpable lesion	39	9.9
Histopathological diagnosis:		
Fibrocystic lesions	82	20.6
Fibroadenoma	131	33.0
Sclerosing adenosis	23	5.8
Papilloma	11	2.7
Hamartoma	1	0.3
Hyperplasia without atypia	42	10.5
Atypical ductal hyperplasia (ADH)	6	1.6
Ductal carcinoma in situ (DCIS)	12	3.0
Invasive ductal cancer	80	20.1
Invasive lobular cancer	6	1.6
Nondiagnostic result	3	0.8

In 98 women breast cancer diagnosis was made based on the histopathological findings from the first VACB samples. Three women, due to the lack of correlation between the clinical manifestations, ultrasound and histopathological findings were qualified for an open surgical biopsy and cancer diagnosis was confirmed (Table III). False negative results were obtained from 3/98 patients (2.3%) who underwent VACB.

Patients diagnosed with atypical ductal hyperplasia or cancer on VACB were qualified for surgical excision. Of 6 patients diagnosed with ADH, 2 were diagnosed with ductal carcinoma in situ. Surgical biopsy revealed an underestimation of 2/6 (33.3%). Of 12 patients with ductal carcinoma in situ, 2 were diagnosed with invasive cancer. Underestimation of DCIS was 2/12 (16.7%). Histopathological findings of the patients are summarized in Table IV.

**Table II.** Morphology of breast lesions qualified for VACB and their BIRADS classification

Structure/BIRADS	No. of patients	Percentage of patients
Nodule/mass	361	90.9
Distortion	22	5.5
Complex cyst	14	3.6
<b>Total</b>	<b>397</b>	<b>100</b>
BIRADS 3	17	4.3
BIRADS 4a	291	73.3
BIRADS 4b	10	2.5
BIRADS 4c	6	1.2
BIRADS 5	80	18.5
<b>Total</b>	<b>397</b>	<b>100</b>

**Table III.** Clinical and pathological features of breast cancers in patients with false negative result of VACB

Case	Ultrasound	Diameter	BIRADS	VACB	Open surgical biopsy
1	Hypoechogenic nodule	10 mm × 8 mm	4c	Sclerosing adenosis	Invasive lobular cancer
2	Distortion	9 mm × 6 mm	4c	Unspecific inflammatory lesions	Invasive ductal cancer
3	Hypoechogenic nodule	14 mm × 7 mm	5	Fibrosis	Invasive ductal cancer

**Table IV.** Cases of ADH and DCIS on VACB that were upgraded to DCIS or invasive cancer on surgical excision

Histopathological findings after VACB	No. of patients	Histopathological findings after open surgical biopsy	No. of patients	Underestimation [%]
ADH	6	Hyperplasia without atypia	4	33.3
		DCIS	2	
DCIS	12	DCIS	10	16.7
		Invasive cancer	2	

In the first 24 h after the biopsy the patients underwent ultrasound examination which detected hematoma in the biopsy site in 37/397 women (9.3%), ranging from 8 mm to 34 mm (mean: 16 mm). None of the hematomas required surgical intervention.

## Discussion

Breast cancer is the most common malignant neoplasm in women in Poland and the second most frequent cause of death due to malignant neoplasm in this group. Developments in imaging diagnostics and relatively good availability of mammography and ultrasound increased detection of breast focal lesions in the pre-clinical stage. The differential diagnosis of small, impalpable focal lesions suspected of a malignant process is especially difficult. Until recently, the golden standard in such cases was an open surgical biopsy. However, possible complications, the length of the procedure, high costs, scars, and frequently breast deformation have led to a search for less invasive and less expensive methods. Vacuum-assisted core biopsy proves to be a method that eliminates or to a large extent limits these disadvantages [6-8]. It is an efficient, minimally invasive, relatively inexpensive procedure with a good cosmetic effect and a low complication rate [9-13].

Similarly to minimally invasive techniques used in the treatment of other organs, VACB is in some cases an interesting alternative to a more extended surgical

procedure [14, 15]. This procedure is gradually taking over the so far commonly used fine needle aspiration biopsy whose main disadvantage is a high rate of nondiagnostic results (4-35.4%) and false negative results (2.6-20%) [6, 16-18]. Vacuum-assisted core biopsy provides multiple quality samples from a single insertion compared to a traditional core biopsy [2, 7]. The diagnostic accuracy of the mammotome biopsy is 98-100% for breast lumps [1, 6, 19]. The open surgical biopsy yields similar results, but it is more invasive and costly. In our patients, a sufficient number of samples for histopathological examination was obtained in the first biopsy from 394 patients (99.2%). Only in 3 cases (0.8%) was the result nondiagnostic. Repeat breast biopsy in these cases revealed fibrocysts. Our results were consistent with the observation of other authors. For example, in his study, Casano *et al.* obtained a sufficient number of samples for histopathological verification in the first ultrasound-guided biopsy from all 404 of his patients [20]. Women diagnosed with a benign lesion (fibroadenoma, fibrocysts, adenosis, papillomas, hyperplasia without atypia) without a suspected malignant process in imaging examinations were followed up for several months with mammograms, digital mammograms, ultrasound, or MR. In none of the cases was a recurrence or progress revealed, which confirms that further verification with an open surgical biopsy was not necessary in these cases. Our observations

are in this respect consistent with those of other authors [5, 6, 18, 20-22].

An ultrasound-guided vacuum-assisted core biopsy can have therapeutic value. It gives excellent cosmetic results, is well tolerated and is associated with low complication rates compared to surgery [20]. In our study, we entirely removed in ultrasound-guided VACB all lesions with low risk of malignancy in imaging examinations with a diameter up to 15 mm in 94.5% of women, similarly as Plantade, who excised entire lesions in 98.1% of his patients [23]. However, if the patients are diagnosed with a benign lesion during the biopsy and the lesions are classified as BIRADS 4b, 4c, 5 in imaging examinations, it is necessary to repeat the biopsy or perform open surgical biopsy [20, 24] due to a high risk of overlooking cancer. In our patients, 2 lesions were classified as BIRADS 4c, and 1 BIRADS 5 tumor was found to be benign on biopsy (Table IV), although the final diagnosis established after surgical biopsy was invasive cancer.

Atypical ductal hyperplasia (ADH) is a proliferative lesion that often coexists with breast cancer and substantially increases the risk of breast cancer. In other studies, the number of diagnosed breast cancer cases after surgery in patients who were earlier diagnosed with ADH in VACB reaches 68% [25], compared to 33.3% in our group. Of our 12 patients diagnosed with ductal carcinoma in situ by VACB, surgical biopsy revealed invasive cancer in 2 cases (underestimation was 16.7%). These results confirm the necessity of surgery in ADH and DCIS patients who underwent ultrasound-guided mammotome biopsy.

Of 98 breast cancer cases diagnosed by biopsy, 28 were impalpable. The results indicate high value of ultrasound-guided VACB in diagnosis of the pre-clinical stage of breast cancer. In case of suspected malignant lesions, VACB allows one to verify the diagnosis and define the receptor status [6]. It helps to make correct a therapeutic decision whether to administer systemic palliative treatment or induction therapy. Complications after vacuum-assisted core biopsy are rare, ranging from 1.3% to 9% [6, 23, 24]. The most common, hematoma in the biopsy site, occurred in 7.3% of our patients. None of them required surgical intervention. We did not observe any complications described in the literature, such as hemorrhage from the biopsy site, hematomas requiring a revision, pneumothorax, damage to skin away from the needle puncture point or infections.

## Conclusions

The results obtained from our study confirm high efficiency of ultrasound-guided VACB in the differential diagnosis of breast focal lesions, including impalpable lesions. It is a safe method with a low complication rate and a useful alternative to the open surgical biopsy for benign lesions with a diameter not exceeding 15 mm. Vacuum-assisted core biopsy is therefore recommended as a standard and a method of choice in the diagnosis of breast lesions.

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